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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,844	08/06/2001	Shujath M. Ali	DEX-0176	7509
32800 7590 11/05/2007 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			NOTIFICATION DATE 11/05/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 09/787,844	Applicant(s) ALI ET AL.	
	Examiner MISOOK YU	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 9, 14, 15, 18, 19, 23, 24, and 26-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 14, 15, 18, 19, 23, 24, and 26-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 8, 9, 14, 15, 18, 19, 23, 24, and 26-24 are pending and under consideration.

Claim Rejections - 35 USC § 112, Maintained

Claims 8, 9, 14, 15, 18, 19, 23, 24, 26-24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention as drawn to a method of imaging of a gynecologic cancer using an monoclonal or polyclonal antibody which specifically binds to a native protein expressed by SEQ ID NO: 1 (base claim 8), wherein said antibody is labeled (claim 9), or method of delivering a derivatized antibody to a gynecologic cancer cell (claims 14, and 15) or gynecological tumor in vivo (claims 18 and 19), wherein claims 23, 24, 26, 27 characterizes that the protein of the base claims to be protease with active domains, wherein claims 28-45 specifies various gynecologic cancer.

Applicant argues that the claimed invention is drawn to method of targeting a native protein expressed by SEQ ID NO:1, and the Examiner's characterization of the specification as originally filed teach instant SEQ ID NO: 2 is encoded by SEQ ID NO: 1 is incorrect, and a native protein encoded by the instant SEQ ID NO: 1 also encompasses the two proteins (one with 314 amino acids and 1081 amino acids proteins below).

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Query Match 96.4%; Score 1728; DB 1; Length 314;
Best Local Similarity 100.0%; Pred. No. 1.2e-147;
Matches 314; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 14 MGARGALLLALLLARAGLRKPESQEAAPLSGPGCRRVITSRIVGGEDAELGRWPWQGS LR 73
|||||
Db 1 MGARGALLLALLLARAGLRKPESQEAAPLSGPGCRRVITSRIVGGEDAELGRWPWQGS LR 60
|||||

Qy 74 LWD SHVCGVSLLSHRWALTAHCFETYSDLSDPGMMVQFGQLTSMPSFWSLQAYYTRYF 133
|||||
Db 61 LWD SHVCGVSLLSHRWALTAHCFETYSDLSDPGMMVQFGQLTSMPSFWSLQAYYTRYF 120
|||||

Qy 134 VSN IYLSPRYLGN SPYDIALVKLSAPVTTYTKHIQPICLQASTFEFENRTDCWVTG WGYIK 193
|||||
Db 121 VSN IYLSPRYLGN SPYDIALVKLSAPVTTYTKHIQPICLQASTFEFENRTDCWVTG WGYIK 180
|||||

Qy 194 EDEALPSPHTLQEVQVAI INNSMCNHLFLKYSFRKDI FGDMVCAGNAQGGKDACFGDSGG 253
|||||
Db 181 EDEALPSPHTLQEVQVAI INNSMCNHLFLKYSFRKDI FGDMVCAGNAQGGKDACFGDSGG 240
|||||

Qy 254 PLACNKNGLWYQIGVVSNGVGCGRPNRPGVYTNISHHFEWIKLMAQSGMSQPDPSWPLL 313
|||||
Db 241 PLACNKNGLWYQIGVVSNGVGCGRPNRPGVYTNISHHFEWIKLMAQSGMSQPDPSWPLL 300
|||||

Qy 314 FFPLLWALPLLGPV 327
|||||
Db 301 FFPLLWALPLLGPV 314
|||||

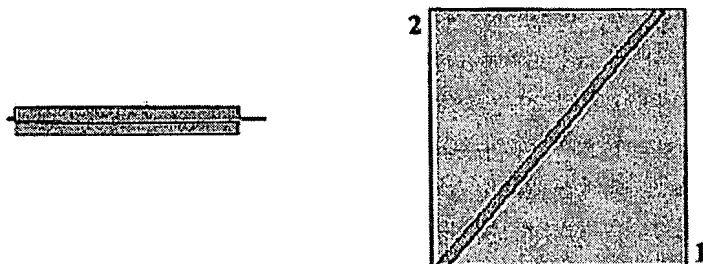
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Sequence 1: DEX0044_1

Length = 1081 (1 .. 1081)

Sequence 2: Q9Y6M0_TEST_HUMAN

Length = 314 (1 .. 314)



NOTE: Bitscore and expect value are calculated based on the size of the nr database.



Score = 670 bits (1728), Expect = 0.0
 Identities = 314/314 (100%), Positives = 314/314 (100%), Gaps = 0/314 (0%)
 Frame = +1

Query	40	MGARGALLLALLARAGLRKPESQEAAPLSGPGCRRVITSRIVGGEDAELGRWFWQGSRLR	219
		MGARGALLLALLARAGLRKPESQEAAPLSGPGCRRVITSRIVGGEDAELGRWFWQGSRLR	
Sbjct	1	MGARGALLLALLARAGLRKPESQEAAPLSGPGCRRVITSRIVGGEDAELGRWFWQGSRLR	60
Query	220	LWDSHVCVSLLSHRWALTAAHCFETYSDLSDPGWMVQFGQLTSMPSFWSLQAYYTRYF	399
		LWDSHVCVSLLSHRWALTAAHCFETYSDLSDPGWMVQFGQLTSMPSFWSLQAYYTRYF	
Sbjct	61	LWDSHVCVSLLSHRWALTAAHCFETYSDLSDPGWMVQFGQLTSMPSFWSLQAYYTRYF	120
Query	400	VSNIIYLSPRYLGNSPYDIALVKLSAPVTTYTKHIQPICLQASTFEFENRTDCWVTGWGYIK	579
		VSNIIYLSPRYLGNSPYDIALVKLSAPVTTYTKHIQPICLQASTFEFENRTDCWVTGWGYIK	
Sbjct	121	VSNIIYLSPRYLGNSPYDIALVKLSAPVTTYTKHIQPICLQASTFEFENRTDCWVTGWGYIK	180
Query	580	EDEALPSPHTLQEVQVAIIINSMCNHLFLKYSFRKDI PGDMVCAGNAQGGKDACFGDGGG	759
		EDEALPSPHTLQEVQVAIIINSMCNHLFLKYSFRKDI PGDMVCAGNAQGGKDACFGDGGG	
Sbjct	181	EDEALPSPHTLQEVQVAIIINSMCNHLFLKYSFRKDI PGDMVCAGNAQGGKDACFGDGGG	240

Query	760	PLACNKNGLMYQIGVVSQVGCGRPNRPGVYTNISHHFEWIKLMAQSGMSQPDPSWPLL	939
		PLACNKNGLMYQIGVVSQVGCGRPNRPGVYTNISHHFEWIKLMAQSGMSQPDPSWPLL	
Sbjct	241	PLACNKNGLMYQIGVVSQVGCGRPNRPGVYTNISHHFEWIKLMAQSGMSQPDPSWPLL	300
Query	940	FFPLLWALPLLGPV	981
		FFPLLWALPLLGPV	
Sbjct	301	FFPLLWALPLLGPV	314

CPU time: 0.06 user secs. 0.02 sys. secs 0.08 total secs.

Applicant's arguments have been fully considered but found unpersuasive. The specification as originally filed does not teach any protein having 314 amino acid residues or 1081 amino acids. The sequence listing part of the specification has 3 SEQ ID Nos. None of them is 314 amino acids proteins. If the term "a native protein encoded by SEQ ID NO: 1" is a genus encompassing all three (i.e. 314, 317, and 1081), then the specification is enabled for the genus, not the other two species, (314 and 1081 amino acids proteins). The genus could not be enable the two species in this case because the specific protein structures should have known in order for the specification to be a enabling disclosure.

As stated before in the two previous Office actions, Aloj et al., (2002, Biopolymers. Vol. 66, pages 370-80) teach that in order to target specific molecules inside the body using radiopharmaceuticals such as a radioisotope-labeled antibody, several parameters have to be considered: (1) the target protein should be over-expressed in cancer to be imaged; (2) a radiopharmaceutical should be tested to see whether said radiopharmaceutical specifically binds to the *in vivo* target; (3) how the unbound radiopharmaceutical is cleared for minimizing unwanted high background (note the abstract, and pages 372-373). The instant specification has failed to teach with a reasonable certainty that the protein encoded by SEQ ID NO:1 is a gynecologic cancer antigen while the art (see Hooper et al., above) suggests that the protein encoded by SEQ ID NO:1 is a tumor suppressor. Low et al., (1995, Radiology, vol. 195, pages 391-400) also teach that in order to image an ovarian cancer (a species of a gynecologic cancer), selection of an antibody that specially binds to an ovarian cancer-

associated antigen, is the first necessary step (see page 391 middle column; the authors selected an antibody targeting Tag-72, a previously known ovarian cancer antigen). Low et al., further teach accuracy of imaging using an antibody directed to a cancer antigen has to be evaluated against other known cancer detection methods such as histology or pathology (note page 393 under the heading "Pathologic Proof", and Table 3 at page 396). Likewise, Krag et al., (1993, Arch. Surg. Vol. 128, pages 819-23) teach method of imaging an ovarian cancer using a radio-labeled (i.e. indium 111-labeled) CYT-103 monoclonal antibody requires selection of an antibody capable of binding to an antigen that is over-expressed in an ovarian cancer (see page 820 under the heading "Patients, Materials, and Methods").

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

/Misook Yu/